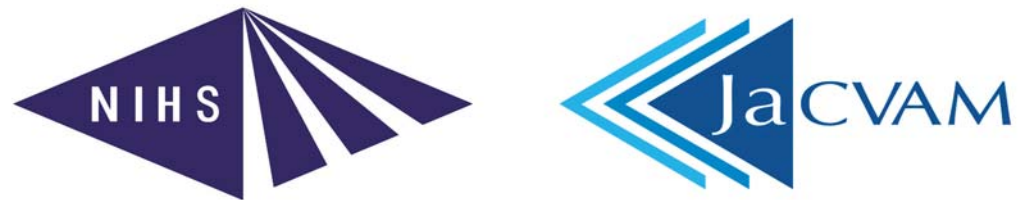


JaCVAM Update



June, 2009
SACATM meeting



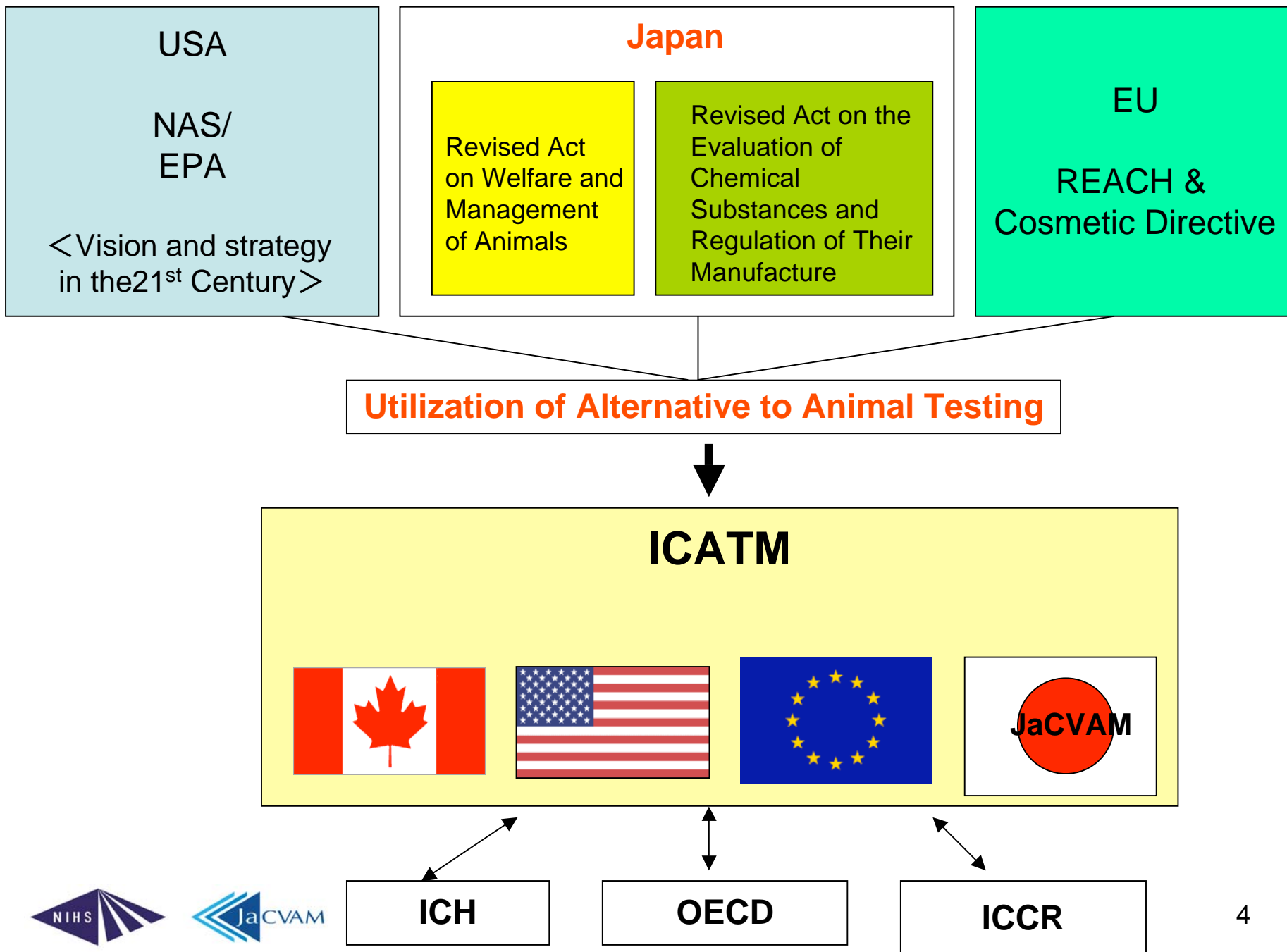
Contents

- ICATM
- Correlation with OECD test guideline
- JaCVAM statement
- JaCVAM regulatory acceptance board
- JaCVAM peer review panel
- On-going of Validation study
- 7th World Congress
- JaCVAM web site

ICATM



Four country representatives signed the international agreement to reduce animal use in toxicity testing. Shown left to right are Linda Birnbaum, David Blakey, Elke Anklam, and Hajime Kojima representing Masahiro Nishijima of Japan. Standing are Marilyn Wind, Michelle Limoli of FDA, and William Stokes. (Photo courtesy of NIH)
Birnbaum signed as the U.S. representative on behalf of the NTP Interagency



Correlation with OECD test guideline

New accepted TG for a Stably Transfected Transcriptional Activation (STTA) Assay for the detection of estrogenic activity of chemicals (April, 2009)

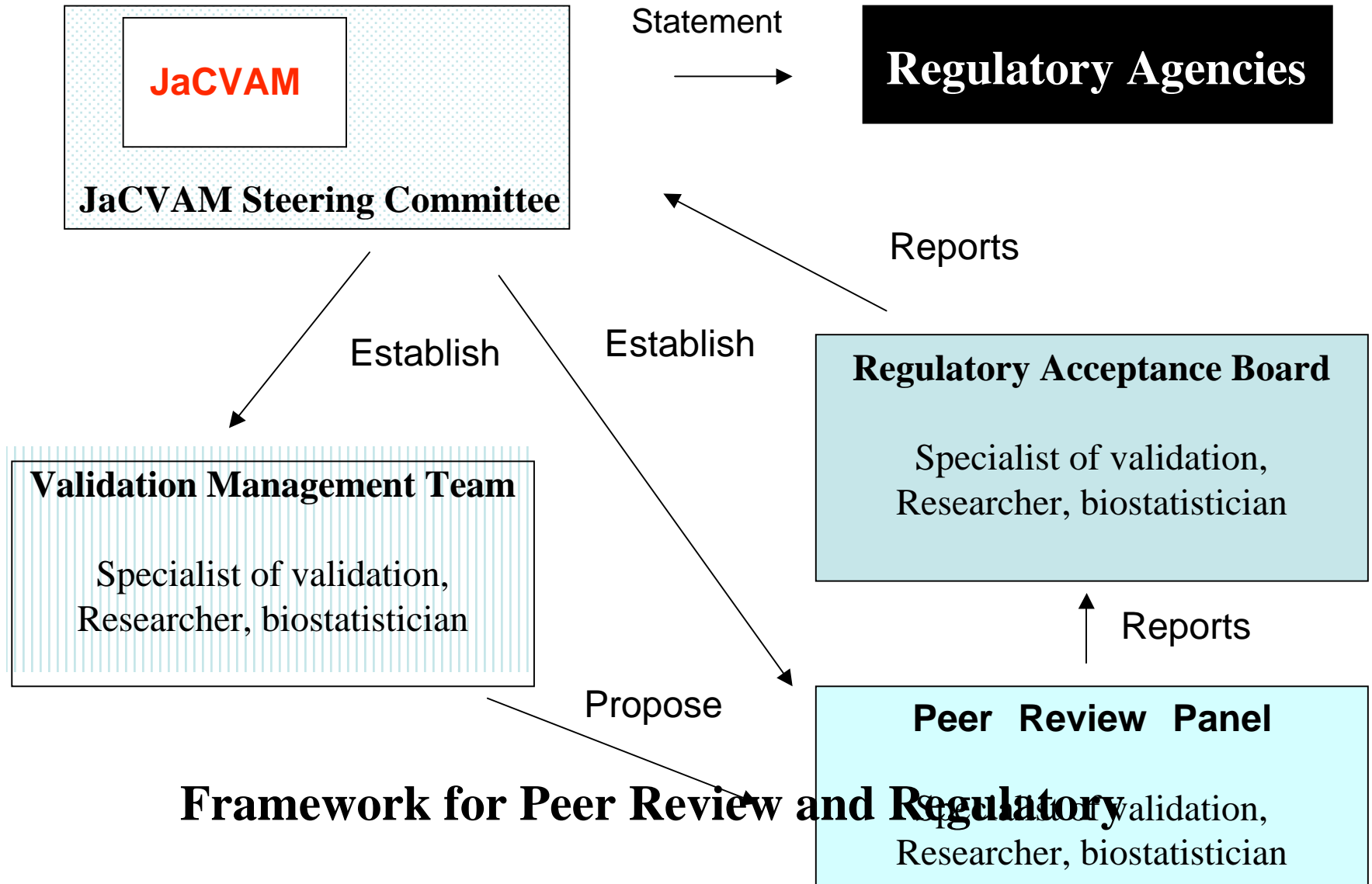
Project 4.34: EDTA Activity - New TG for a stably Transfected Transcriptional Activation (STTA) Assay for the detection of anti-estrogenic activity of chemicals

Project 4.36: New TG: Comet Assay in Genotoxicity Testing

Project 4.26: Cell Transformation Assay using Balb/c 3T3 cell line

Project 4.35: New TG for an *In Vitro* Skin Irritation Assay (LabCyte model)

TG 429: Skin Sensitisation for a Non-Radioisotope version of the Local Lymph Node Assay



Framework for Peer Review and Regulatory Acceptance



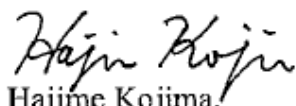
Acceptance of Alternative Methods

JaCVAM statement
on the Vitrolife-Skin™, a 3-dimensional cultured skin model for skin corrosivity testing

At the meeting concerning the above method, held on 22 April and 8 July 2008 at the National Institute of Health Sciences (NIHS), Tokyo, Japan, the non-commission members of the Japanese Center for the Validation of Alternative Methods (JaCVAM) regulatory acceptance board [1] unanimously endorsed the following statement:

Following the review of the results of the the Ministry of Health, Labour and Welfare (MHLW)-funded validation study on the Vitrolife-Skin™ skin corrosivity test coordinated by Japanese Society for Alternative to Animal Experiments (JSAAE), it is concluded that the Vitrolife-Skin™, a 3-dimensional cultured skin model can be used for distinguishing between corrosive and non-corrosive chemicals within the context of the OECD testing guidelines No. 431 on In Vitro Skin Corrosion: Human Skin Model Test.

The JaCVAM regulatory acceptance board has been regularly kept informed of the progress of the study, and this endorsement was based on an assessment of various documents, including, in particular, the report on the results from the study, and also on the evaluation supported by MHLW of the study prepared for the JaCVAM ad hoc peer review panel.



Hajime Kojima,
Director,
JaCVAM,
National Centre for Biological Safety and Research (NCBSR)
NIHS,
Tokyo



Tofu Inoue,
Director,
NCBSR,
NIHS,
Tokyo



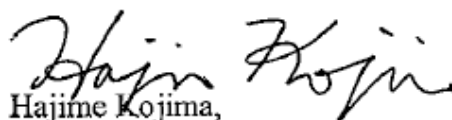
4 August 2008

**JaCVAM statement
on the LLNA-DA for skin sensitization testing**

At the meeting concerning the above method, held on 28 August 2008 at the National Institute of Health Sciences (NIHS), Tokyo, Japan, the noncommission members of the Japanese Center for the Validation of Alternative Methods (JaCVAM) Regulatory Acceptance Board [1] unanimously endorsed the following statement:

Following the review of the results of the Ministry of Health, Labour and Welfare (MHLW)-funded validation study on the LLNA (Local Lymph Node Assay) -DA coordinated by Japanese Society for Alternative to Animal Experiments (JSAAE), it is concluded that the LLNA-DA can be used for distinguishing between sensitizer and non-sensitizer chemicals within the context of the OECD testing guideline No. 429 on Skin sensitization: LLNA.

The JaCVAM Regulatory Acceptance Board has been regularly kept informed of the progress of the study, and this endorsement is based on an assessment of various documents, including, in particular, the report on the results from the study, and also on the evaluation supported by JSAAE of the study prepared for the JaCVAM ad hoc peer review panel.



Hajime Kojima,
Director,
JaCVAM,
National Centre for Biological Safety and Research (NCBSR)
NIHS,
Tokyo



Tetsu Inoue,
Director,
NCBSR,
NIHS,
Tokyo

Accepted methods by the JaCVAM regulatory acceptance board

- The Bovine Corneal Opacity and Permeability (BCOP) Test Method for Identifying Ocular Corrosives and Severe Irritants (Accepted on April 13, 2009)
- The Isolated Chicken Eye (ICE) for Identifying Ocular Corrosives and Severe Irritants (Accepted on April 13, 2009)
- Battery system to predict phototoxicity: Yeast growth Inhibition phototoxicity assay and Red blood cell photohemolysis assay (Accepted on June 1, 2009)

Pending methods by the JaCVAM regulatory acceptance board

- LLNA : BrdU-ELISA
- *In vitro* skin irritation testing

On-going of the JaCVAM peer review

- Immunotoxicity rLLNA (ICCVAM&ECVAM)
- Skin irritation EpiDerm, Skin Ethics (ECVAM)
LabCyte (Japanese)
- Eye irritation Cytotoxicity (Japanese)
Cell function assay : unsolicited)
- Pyrogenicity Five *in vitro* assays (ICCVAM& ECVAM)
- Acute toxicity testing 3T3/NRU(ICCVAM)

On-going of Validation study

- h-CLAT assay (ECVAM/JaCVAM)
- *In vivo/in vitro* Comet assay (ICCVAM/ECVAM/JaCVAM)
- STTA antagonist assay (ECVAM/JaCVAM)
- Lumi-cell assay (ICCVAM/ECVAM/JaCVAM)
- Bhras cell transformation assay (ICCVAM/ECVAM/JaCVAM)

Revised protocol of *In vivo* comet assay

The standard protocol ver.13 should be revised so as

to conform with the **ICH and EFPIA** initiative, i.e. the collaborative study of comet assay that would incorporate it into the **repeat-dose general toxicity study** in order to comply with the 3Rs principles (reduction, refinement, and replacement of animals used in experiments and education). Such a revision would involve 3 treatments (0, 24, and 45 h) before sacrificing the animals at 48 h after the first treatment instead of 2 treatments as described in the protocol ver. 13. This protocol, once revised, can be then used for the **combination/integration study comprised of the micronucleus assay and the comet assay.**

WC7 oral presentation

- August 31, Lunch session 13.50-14.50
Good Cell Culture practices
- August 31, 14:50-17:20
Current and evolving concepts for the validation of safety assessment method
- September 1, 10.00-11.00
Status Report on ICATM
- September 1, Lunch session 13.40- 14.40
Recent progress and future directions in the validation and regulatory acceptance of alternative test methods that reduce, refine and replace animal use
- September 1, 14:45-17:15
Cosmetics

WC7 poster presentation

- ID203 “ADEQUATE CONDITIONS FOR PERFORMANCE OF **COMET ASSAY** USING 3-DIMENSIONAL HUMAN EPIDERMAL MODEL”
- ID204 “IN VIVO **COMET ASSAY**: UPDATE ON THE ON-GOING INTERNATIONAL VALIDATION STUDY”
- ID205 “**JACVAM STATEMENT** ON NEW ALTERNATIVE TO ANIMAL TESTING”
- ID206 “REVIEW OF AN ALTERNATIVE TO ANIMAL TESTING FOR SAFETY EVALUATION OF COSMETIC INGREDIENTS USING **QUASI-DRUG**”
- ID 207 “VALIDATION OF LABCYTE EPI-MODEL24, AN IN VITRO ASSAY FOR DETECTING **SKIN IRRITANTS***”
- ID423 “INTERNATIONAL VALIDATION STUDY OF THE IN VITRO ALKALINE **COMET ASSAY**”
- ID424 “CELL SURFACE MARKER OF **CORNEAL EPITHELIUM STEM CELLS** AND CULTURE”
- ID?? “International validation study of **ERa STTA antagonist** assay using HeLa9930”





JaCVAMとは



JaCVAMの活動



JaCVAM関連委員会



試験法の公募

JaCVAMは、化学物質等の安全性評価における動物実験の3Rs※の促進と国際協調を重視した新規動物実験代替法の公定化を進めます。

※動物実験の3Rs・・・ Reduction (of animal use)

Refinement (to lessen pain or distress and to enhance animal well-being)

Replacement (of an animal test with one that uses non-animal systems or phylo-genetically lower species)
(OECD GD34)

News

- ② JaCVAM第2回ワークショップの要旨集、発表原稿を掲載
(2009.05.25)
- ② ICATMの調印式が執り行われました(2009.04.27)
- ② OECDで新たに2つのテストガイドラインを認証(2009.5.13)
- ② 科学新聞に動物実験代替法に関する記事が掲載されました
(2009年4月3日掲載)
- ② 朝日新聞にJaCVAM関連記事が掲載されました(2009年4月24日掲載)

Contents

- ② JaCVAMとは
ご挨拶 / 設立目的と役割 / 運営組織 / 研究活動 /
用語解説 / 活動規則案
- ② JaCVAMの活動
進行中の試験一覧マップ / 行政に提案した新規試験法一覧
- ② JaCVAM関連委員会
- ② 新規試験法、改定試験法の公募
- ② 動物実験について
- ② お問い合わせフォーム
- ② 関連リンク集

**JaCVAMが行政に提案した
新規試験法一覧**



Google 検索



WWW を検索



jaqvam.jpを検索

JaCVAMの活動

[TOP](#) > [JaCVAMの活動](#) > [進行中の試験一覧マップ](#)

進行中の試験一覧マップ

分類	試験名 (クリックで詳細表示)	バリデーション 研究	専門家による第 三者評価	JaCVAM評価 会議等	行政への提案	OECD化学品テスト ガイドライン	関与機関
01 腐食性 試験	(1) Vitrolife-Skinを用いた細胞毒性	2005年2月 	2008年6月 	2008年6月 	2008年8月 	OECD TG No.431 	日本動物実験代替法学会
02 光毒性 試験	(1) 3T3-NRU	ZEBETで終了 	2004年11月 	評価中 		OECD TG No.432 	
	(2) 酵母光生育阻害試験と赤血球の溶血試験	2004年8月 	評価中 				日本動物実験代替法学会
03 皮膚感作性試験	(1) LLNA-DA: マウスリンパ節中のATP量の変化を指標とする方法	2007年6月 	2008年2月 	2008年10月 	2008年11月 		日本動物実験代替法学会

Thank you for your attention

